

REMARKS

Applicant respectfully requests reconsideration. Claims 1-35 were previously pending in this application. By this amendment, Applicant is canceling claims 21 and 35 without prejudice or disclaimer. Claims 1, 11, 17, 19, 20, 22-24 and 29 have been amended. New claims 36-39 have been added. Support for the claim amendments and new claims can be found throughout the specification (for example, on page 18, lines 19-24) and in the claims originally filed. As a result, claims 1-20, 22-34 and 36-39 are pending for examination with claims 1 and 20 being independent claims. No new matter has been added.

Priority

Applicant respectfully thanks the Examiner for acknowledging Applicant's claim for the benefit of a prior-filed application. Applicant has amended the specification to recite the priority claim at the beginning of the specification.

Claim Objections

The Examiner objected to claim 1, because of an alleged incomplete final step. Without conceding the correctness of this objection, Applicant has amended claim 1.

The Examiner objected to claims 20, 21 and 35 as allegedly being of improper dependent form. Without conceding the correctness of this objection, Applicant has amended claim 20 so that it is rewritten in independent format. In addition, Applicant has canceled claims 21 and 35.

The Examiner has also objected to claim 21 for the phrase "further comprising wherein" and the phrase "as a result of said nuclear transfer procedure". Since claim 21 has been canceled, this objection is now moot.

Accordingly, withdrawal of the objections is respectfully requested.

Rejection under 35 U.S.C. §101

The Examiner rejected claims 20 and 35 under 35 U.S.C. 101 because the claimed invention allegedly is directed to non-statutory subject matter. According to the Examiner, the claims are directed to offspring of the methods of claim 1 and claims 24 or 29, respectively.

Such an offspring is alleged by the Examiner to be indistinguishable from the mammal from which it is derived and is also indistinguishable from any other mammal of the same species.

Applicant respectfully traverses. According to MPEP 2105, the decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. §101. It is clear from the Supreme Court decision that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention. Claim 20 pertains to the offspring generated by the described method. Clearly, the offspring is "the result of human intervention" and is, therefore, patentable.

Accordingly, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112, 1st paragraph

The Examiner rejected claims 1-20, 22 and 23 under 35 U.S.C. §112, 1st paragraph, for allegedly failing to comply with the enablement requirement. According to the Examiner, the specification fails to provide any guidance with respect to cloning primates.

Applicant respectfully traverses. Not only does the specification provide sufficient guidance for performing the methods of the rejected claims, at the time of filing, techniques that could be used for cloning primates were known to those of ordinary skill in the art (See, for example, Meng et al. *Biol. Reprod.* 1997, 2: 454 and Chan et al. *Science* 2001, 291: 309). Meng et al. teach a method for the generation of rhesus monkeys by nuclear transfer, and Chan et al. teach the production of transgenic rhesus monkeys. Therefore, Applicant maintains that the Examiner's rejection of the claims on this basis cannot be sustained.

The Examiner has also argued that the specification does not teach *in vitro* transformation of fetal or adult somatic cells immediately prior to nuclear transfer. Applicant disagrees with the Examiner's conclusion. The art quoted by the Examiner pertains to the generation of genetic modifications of somatic cells in culture, and contrary to the Examiner's conclusion, demonstrates that it is possible to alter somatic cells in culture with the knowledge of those of ordinary skill in the art. Certainly, the Examiner has not demonstrated that undue

experimentation is required to alter somatic cells and use them and/or their nuclei in the methods of the claims.

Further, according to the Examiner, the specification does not teach one of ordinary skill in the art how to use a transgenic non-human mammal that does not express the transgene. Applicant respectfully traverses. However, without conceding the correctness of the Examiner's rejection, Applicant has amended claim 20 and believes that the rejection is now moot.

Accordingly, Applicant respectfully requests withdrawal of this rejection.

The Examiner also rejected claims 21 and 24-35 under 35 U.S.C. §112, 1st paragraph, for allegedly failing to comply with the enablement requirement. According to the Examiner, claim 21 is drawn to chimeric offspring without method steps that would lead to chimerism. The Examiner argued that claims 24-35 are not enabled because the specification allegedly fails to provide guidance as to how to carry out nuclear transfer using a haploid oocyte as a nuclear donor.

Without conceding the correctness of the Examiner's rejection, Applicant has canceled claims 21 and 35 and amended claims 24 and 29 and believes that the rejection is now moot.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112, 2nd paragraph

The Examiner rejected claims 1-35 under 35 U.S.C. 112, 2nd paragraph, for allegedly being indefinite.

The Examiner has alleged that claim 1 is unclear because of the use of the term 'transgenic' in steps (vi) and (vii) of the claim. Without conceding the correctness of the Examiner's position, Applicant has amended claim 1 and introduced the limitation 'from a transgenic non-human mammal' in step (i).

The Examiner has also alleged that there is insufficient antecedent basis for 'the desired differentiated cell or cell nucleus' in line 8 of claim 1. Without conceding the correctness of the Examiner's position, Applicant has amended steps (i) and (iv) of the claim.

According to the Examiner there is insufficient antecedent basis for the limitation 'the cell-couplet' in line 10. Without conceding the correctness of the Examiner's rejection, Applicant has amended step (iv) of claim 1 to recite 'to form a cell-couplet'.

According to the Examiner, claim 1 is incomplete as written, because the method steps do not relate back to the preamble in a positive process. Without conceding the correctness of this rejection, Applicant has amended the preamble of claim 1.

According to the Examiner, claim 1 is unclear because the method steps are allegedly not commensurate in scope with the preamble. Since the preamble has been amended, the rejection is now moot.

According to the Examiner, claim 17 is unclear because there is allegedly no antecedent basis for the term 'the fetus'. Without conceding the correctness of this rejection, Applicant has amended claim 17.

According to the Examiner, claim 19 is allegedly unclear. Applicant respectfully traverses. A step in the method of the claim comprises taking a genome from the 'differentiated mammalian cell from a transgenic non-human mammal' and transferring it into an enucleated oocyte. The genome of 'the differentiated mammalian cell' is considered the parent cell. Even if the genome of 'the differentiated mammalian cell' is modified, as stated in the limitation of claim 19, the genome is still the genome of the parent cell. The transgenic embryos produced according to the method of claim 1 will have a genome that is identical to the source of the donor nucleus, namely 'the differentiated mammalian cell'. Applicant maintains that the method is sufficiently clear.

According to the Examiner there is insufficient antecedent basis for the limitation 'offspring' in claims 20, 21 and 35. Without conceding the correctness of the Examiner's position, claim 20 has been amended and claims 21 and 35 have been canceled.

According to the Examiner there is insufficient antecedent basis for the limitation 'the cloning protocol' in claims 22 and 23. Applicant has amended claims 22 and 23 without conceding the correctness of this rejection.

According to the Examiner, claims 24 and 29 are unclear. Applicant has amended claims 24 and 29 without conceding the correctness of this rejection.

According to the Examiner, claim 17 is unclear because there is no antecedent basis for the term 'the fetus'. Applicant has already addressed this rejection above.

Accordingly, withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. §102

The Examiner rejected claims 20 and 35 under 35 U.S.C. §102(b) as allegedly being anticipated by Wilmut (1997, IDS).

Without conceding the correctness of the Examiner's position, Applicant has amended claim 20 and canceled claim 35. Applicant, therefore, maintains that this rejection is now moot.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 20 and 21 under 35 U.S.C. §102(b) as allegedly being anticipated by Mansour et al. (1993, Development, 117: 13-28). According to the Examiner, Mansour teaches a method of making genetically modified mice that results in an intermediate product of chimeric, transgenic mice, as well as a final product of non-chimeric, transgenic mice.

Applicant respectfully traverses. The Examiner has not met her burden in showing that the rejected claims are anticipated by Mansour et al. Applicant believes that the Examiner has not sufficiently demonstrated that the product of the rejected claims or the process by which the product is made is the same as the product or process of the reference cited.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103

The Examiner rejected claims 1, 2, 5-9, 11, 13, 17, 19, 20 and 22 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schnieke (1997, Science, 278: 2130-2133) as evidenced by Wilmut (1997, IDS), by Campbell (1996, IDS) and by Campbell (1994, Biology of Reproduction, 50:1385-1393), in view of Zakhartchenko (1999, IDS) or Wells (1999, IDS).

Applicant respectfully traverses. The Examiner, in her arguments, has not demonstrated that any of the references teach at least the limitations of part (vi) of claim 1 or the limitation that the desired differentiated mammalian cell is from a transgenic non-human mammal.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 3, 4, 10, 12, 14 and 15 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schnieke (1997, Science, 278: 2130-2133) as evidenced by Wilmut (1997, IDS), by Campbell (1996, IDS) and by Campbell (1994, Biology of Reproduction, 50:1385-1393), in view of Zakhartchenko (1999, IDS) or Wells (1999, IDS), and further in view of Campbell (WO 00/42174).

Applicant respectfully traverses. Again, as argued above the Examiner, in her arguments, has not demonstrated that any of the references teach at least the limitations of part (vi) of claim 1 or the limitation that the desired differentiated mammalian cell is from a transgenic non-human mammal.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claim 16 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schnieke (1997, Science, 278: 2130-2133) as evidenced by Wilmut (1997, IDS), by Campbell (1996, IDS) and by Campbell (1994, Biology of Reproduction, 50:1385-1393), in view of Zakhartchenko (1999, IDS) or Wells (1999, IDS), and further in view of Cibelli (1998, IDS).

Applicant respectfully traverses. Again, as argued above the Examiner, in her arguments, has not demonstrated that any of the references teach at least the limitations of part (vi) of claim 1 or the limitation that the desired differentiated mammalian cell is from a transgenic non-human mammal.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 14 and 18 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schnieke (1997, Science, 278: 2130-2133) as evidenced by Wilmut (1997, IDS), by Campbell (1996, IDS) and by Campbell (1994, Biology of Reproduction, 50:1385-1393), in view of Zakhartchenko (1999, IDS) or Wells (1999, IDS), and further in view of DeSousa (US 6,548,741).

Applicant respectfully traverses. Again, as argued above the Examiner, in her arguments, has not demonstrated that any of the references teach at least the limitations of part (vi) of claim

1 or the limitation that the desired differentiated mammalian cell is from a transgenic non-human mammal.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claim 23 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schnieke (1997, Science, 278: 2130-2133) as evidenced by Wilmut (1997, IDS), by Campbell (1996, IDS) and by Campbell (1994, Biology of Reproduction, 50:1385-1393), in view of Zakhartchenko (1999, IDS) or Wells (1999, IDS), and further in view of Park (2001, IDS).

Applicant respectfully traverses. Again, as argued above the Examiner, in her arguments, has not demonstrated that any of the references teach at least the limitations of part (vi) of claim 1 or the limitation that the desired differentiated mammalian cell is from a transgenic non-human mammal.


Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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